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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,812	01/18/2002	Michael G. Walker	PB-0017 US	4709

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,812	WALKER ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. The following applies to groups 3-22: Prior to setting forth the restriction requirement, it is noted that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461,198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unit of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the products are polynucleotides (SEQ ID NOS: 1-5) that appear to encode separate and distinct polypeptide products, which differ in structure and origin to such an extent that non-coextensive searches are required, and that the polynucleotides are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility. As such, the structurally different polypeptides and antibodies, and methods of using the polypeptides and antibodies have been restricted each from the other.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-3, 9, 10 and 11, drawn to a combination comprising a plurality of cDNAs that are induced by retinoic acid wherein the cDNAs have the nucleic acid sequences of SEQ ID Nos: 1-5, or to isolated cDNA selected from SEQ ID Nos: 1-5, vectors, host cells and methods of making proteins, classified in class 536, subclass 23.5, class 435, subclass 69.1, 3201, 325.

Group 2. Claims 4-8, drawn to methods of using a combination of cDNAs to screen a plurality of molecules and compounds to identify at least one molecule or compound that specifically binds a cDNA of the combination, classified in class 435, subclass 6.

Groups 3-7. Claims 12 and 13, drawn to purified proteins, where group 3 is drawn to a protein encoded by SEQ ID NO: 1, group 4 is drawn to a protein encoded by SEQ ID NO: 2, group 5 is drawn to a protein encoded by SEQ ID NO: 3, group 6 is drawn to a protein encoded by SEQ ID NO: 4, group 7 is drawn to a protein encoded by SEQ ID NO: 5, classified in class 530, subclass 350.

Groups 8-12. Claims 14 and 15, drawn to methods of using purified proteins to screen for molecules to identify at least one ligand that binds to the protein, where group 8 is drawn to methods using a protein encoded by SEQ ID NO: 1, group 9 is drawn to methods using a protein encoded by SEQ ID NO: 2, group 10 is drawn to methods using a protein encoded by SEQ ID NO: 3, group 11 is drawn to methods using a protein encoded by SEQ ID NO: 4, group 12 is

drawn to methods using a protein encoded by SEQ ID NO: 5, classified in class 436, subclass 501.

Groups 13-17. Claims 16 and 17, drawn to antibodies, where group 13 is drawn to an antibody that binds to a protein encoded by SEQ ID NO: 1, group 4 is drawn to an antibody that binds to a protein encoded by SEQ ID NO: 2, group 14 is drawn to an antibody that binds to a protein encoded by SEQ ID NO: 3, group 15 is drawn to an antibody that binds to a protein encoded by SEQ ID NO: 4, group 16 is drawn to an antibody that binds to a protein encoded by SEQ ID NO: 17, classified in class 530, subclass 387.1.

Groups 18-22. Claims 18-20, drawn to methods for using an antibody, where group 18 is drawn to a method for using an antibody that binds to a protein encoded by SEQ ID NO: 1, group 19 is drawn to a method for using an antibody that binds to a protein encoded by SEQ ID NO: 2, group 20 is drawn to a method for using an antibody that binds to a protein encoded by SEQ ID NO: 3, group 21 is drawn to a method for using an antibody that binds to a protein encoded by SEQ ID NO: 4, group 22 is drawn to a method for using an antibody that binds to a protein encoded by SEQ ID NO: 5, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons.

Invention groups 1 and the protein groups 3-7, and the antibody groups 13-17 are patentably distinct products.

The polypeptides of groups 3-7 and polynucleotides of group 1 are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, while the polypeptides of groups 3-7 can made by methods using some, but not all, of the polynucleotides that fall within the scope of group 1, they can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups 1 and groups 3-7 are patentably distinct.

Furthermore, searching the inventions of groups 1 and any of 3-7 together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups 1 and groups 3-7 have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups 1 and any of groups 3-7 together.

The polypeptides of any of groups 3-7 and the antibodies of any of groups 13-17 are patentably distinct for the following reasons:

While the inventions of both group sets 3-7 and group sets 13-17 are polypeptides, in this instance the polypeptides of groups 3-7is a single chain molecule that has a particular biological function, whereas the polypeptide of groups 13-17 encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptides of group sets 3-7 and the antibodies of group 13-17 are structurally distinct molecules; any relationship between a polypeptides of group sets 3-7 and an antibody of from any of groups 13-17 is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions of groups 3-7 and groups 13-17 would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of groups 13-17. Furthermore, antibodies which bind to an epitope of a polypeptide of any of groups 3-7 may be known even if a polypeptide of any of groups 13-17 is novel. In addition, the technical literature search for the polypeptide of any of groups 3-7 and the antibody of any of groups 13-17 are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotides of group 1 and the antibodies of groups 13-17 are patentably distinct for the following reasons. The antibodies of groups 13-17 includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibodies of groups 13-17 which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotides of group 1 will not encode an antibody of any of the groups 13-17, and the antibody of any of the groups 13-17 cannot be encoded by a polynucleotide of group 1. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group 1 and any of groups 13-17 would impose a serious search burden since a search of the polynucleotide of group 1 is would not be used to determine the patentability of an antibody of any of groups 13-17, and vice-versa.

Inventions 2, group set 8-12, and group set 18-22 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The

method of using a polynucleotide or a combination of polynucleotides (group 1), the method of using a polypeptide (groups 8-12), and the method of using an antibody (groups 18-22) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for each of the methods differs significantly. Therefore, each method is divergent in materials and steps. For these reasons the groups 2, 8-12 and 18-22 are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups 2, 8-12 and 18-22 have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups 1, 8-12 and 18-22 together.

Inventions 1 and 2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group 1 can be used to make recombinant proteins as opposed to its use in methods of screening for compounds that bind to a polynucleotide.

Searching the inventions of Groups 1 and 2 together would impose serious search burden. The inventions of Groups 1 and 2 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of screening for compounds that bind to a polynucleotide are not coextensive. The search for

group 2 would require a text search for the method of screening for molecules that bind to a polynucleotide in addition to an oligonucleotide search of a polynucleotide or its complements or a combination of the polynucleotides. Moreover, even if the polynucleotide product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

Inventions 1 and either 8-12 or 18-22 are unrelated because the product of group 1 is not used or otherwise involved in the process of groups 8-12 or 18-22.

Inventions 3-17 and 8-12 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used to make an antibody by injection in a mammal, which is a method that is materially different from the method of groups 8-12.

Searching the inventions of any of Groups 3-7 and with the corresponding group from groups 8-12 together would impose serious search burden. The inventions of Groups 3-7 and 8-12 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the methods of screening for a pluralityof molecules are not coextensive. The search for groups 8-12 would require a text search for the method of screening for ligands, which is not a search that is required in searching groups 3-7. Moreover, even if the polypeptide product were known, the method of screening that uses the product may be novel and unobvious in view of the preamble or active steps.

Inventions 3-7 and 18-22 are unrelated because the products of groups 3-7 is not used or otherwise involved in the processes of groups 18-22.

Inventions 13-17 and 18-22 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Groups 13-17 can be used in a therapeutic method to confer adoptive immunity to a mammal, which is a method that is materially different from the methods of groups 18-22.

Searching the inventions of any of Groups 13-17 and any of inventions 18-22 together would impose serious search burden. The inventions of Groups 13-17 and 18-22 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibodies and the methods of screening and purifying a protein are not coextensive. Moreover, even if the antibody product were known, the method of screening which uses the product may be novel and unobvious in view of the preamble or active steps.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
March 21, 2005

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER